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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/155,642 10/02/98 LINDAHL

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EXAMINER

OKE, V

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application N .

09/155,642

Applicant(s)

LINDAHL ET AL.

Examiner

Victor O. Oke

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-28 and 32-54 is/are pending in the application.
- 4a) Of the above claim(s) 6, 12-15, 18-21, 23, 41, 43-46, 50 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 16-17, 22, 24-28, 32-40, 42, 47-49 and 52-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 17) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

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DETAILED ACTION

Response to Arguments

1. Applicant's election with traverse in paper Number 7 submitted January 4, 2000 of a solid composition comprising the following species is acknowledged:

- (i) an unsaturated fatty acid alcohol, which is an unsaturated C₁₈ fatty acid alcohol, preferably oleyl alcohol (see example 1 and claim 5);
- (ii) an alkylene glycol, which is propylene glycol (see Example 1 and claim 11)
- (iii) a viscosity enhancing agent, which is a waxy substance selected from those recited in Claim 16 or Claim 17;
- (iv) a biologically active agent, which is selected from those recited in Example 1, i.e., fluocinonide, clobetasol propionate, or betamethasone valerate. The elected concentration of alkylene glycol is as recited in Claim 2, i.e., more than 12% by weight based on the total weight of the carrier system.

The traversal is on the ground(s) that applicants have made a novel generic discovery of a solid composition for encapsulation of an active agent. This is not found persuasive because the compositions herein employ a wide array of compounds which vary correspondingly in structure and properties. Therefore the compositions herein lack a single general inventive concept and the same special technical features as discussed in the restriction requirement mailed December 21, 1999. Further, the search for all

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species of compounds encompassed by the claimed compositions and methods is unduly burdensome due to their widely varying chemical structures.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 12-15, 18-21, 23, 41, 43-46, and 50-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7 submitted January 4, 2000.

The claims of this application have been examined insofar as they read on the elected species.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-4, 7-11, 16-17, 22, 24-28, 32-40, 42, 47-49 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. US Patent Number 4,299,828 November 1981 (provided by the applicant in the IDS of October 2, 1998) and Cooper et al. US Patent Number 4,552,872 November 1985.

Wang et al. teaches an antiinflammatory lipophilic solid stick formulation employing a corticosteroid, waxes to provide viscosity enhancement, and stiffness and propylene glycol at a concentration which may be over 12%. See the abstract, column 3, especially lines 49-64 and column 4, lines 10-54. Wang et al. also teach the method of making the same formulation and a method of using it to treat a dermatological condition. See same text cited above and claim 14 therein.

The reference does not teach the applicant's particular corticosteroids or the amounts of corticosteroids herein, the specified ranges of amounts of propylene glycol or the use of the unsaturated fatty acid alcohol, oleyl alcohol.

Cooper et al. teaches applicant's elected corticosteroids in amounts of 0.02-5%, 15-99% of propylene glycol and oleyl alcohol as vehicle in a topical composition useful to treat dermatological disorders. See column 7, lines 28-68, and column

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8, lines 31-68 and column 14, composition III. Cooper also teaches the inclusion of a wax to impart substantivity to the composition. See column 10, lines 35-54.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify Wang's lipophilic corticosteroid, solid stick composition by employing Cooper's corticosteroids in amounts herein and propylene glycol in amounts claimed herein.

A person of ordinary skill in the art would have been motivated at the time the invention was made to employ 12-23% of propylene glycol in the instant solid composition because Cooper teaches that propylene glycol is known to be useful in similar amounts. Further, Wang et al. teach the use of amounts of propylene glycol encompassing those herein as a carrier in solid compositions similar to those herein. Additionally, one of ordinary skill in the art would have been motivated to employ applicant's elected corticosteroids in the solid composition herein in amounts employed herein because the corticosteroids are known to be useful in similar topical corticosteroid compositions in the same amounts. See Cooper et al.

The optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor Oke whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday to Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


Victor Oke
3/20/2000


MINNA MOEZIE
PRIMARY EXAMINER